REMARKS

Status of the Claims

Claims 1, 3, 5-7 and 9-21 remain pending herein. Claims 2, 4, 8 and 22-45 have been previously cancelled without prejudice or disclaimer.

A. Rejection of Claims 1, 3, 6 and 9-21 under 35 U.S.C. 103(a) over Datta et al. US 6,338,739 (Datta) in view of Litner US 6,589,286

Claims 1, 3, 6 and 9-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Datta in view of Litner. This rejection is respectfully traversed.

A key concept of the present claims is the control of changes in rigidity of a medical device, e.g., a stent, so that the device becomes decreasingly rigid and increasingly biomechanically compatible with body tissues in contact with the device over a period of time. That concept can not be found in Datta or Litner. *Ex parte Rubin*, 5 U.S.P.Q. 2d, 1461 (BPAI 1987).

Datta teaches stents produced from biodegradable fibers that are readily passed from a body lumen after a predetermined period of time through normal flow of body fluids passing through the lumen, in particular, stents for placement in the urethra. See, e.g., Abstract and the Figures. The fibers have an inner polymeric core and an outer polymeric layer each of which has a degradation rate different from the other. It is much preferred that the outer layer have a slower degradation rate than the inner or core layer. See, e.g., col. 3, lines 43-48: "An important characteristic of the material with is used to make the inner core is that it has a first degradation rate and that this degradation rate is higher or faster than the degradation rate of the outer layer having a second degradation rate." There is no disclosure that the outer layer "controls the rate at which the inner core material becomes flexible upon contact with bodily fluids," as required by the present claims. In other words a critical concept of applicant's claimed invention is not disclosed.

Another critical limitation of the present claims lacking in Datta is that the "inner core material is selected from a metallic material and a ceramic material." For that concept the examiner attempts to turn to Litner.

Litner teaches eustachian tube stents. While the stent components may include biodegradable materials and may degrade at a programmed rate, Litner does not require that they do so. See, e.g., col. 3, lines 27-30 and col. 5, lines 21-22. Litner does teach that the stent described therein may comprise polymeric materials (both natural and synthetic), ceramic materials, composite materials, metals, metal oxides, and combinations of such materials. Col. 5, lines 18-21. Litner, however, does not teach or suggest that all of these materials, including the ceramic materials, metals, and metal oxides are biodegradable. Indeed, Litner only describes polymers as being potential biodegradable materials. See, e.g. claim 9, col. 3, lines 23-25 and col. 5, lines 22 *et seq.*

Moreover, with respect to the propriety of combining the two references, it should be noted that the devices of Litner are eustachian tube stents, which are quite different in structure from the urological stents of Datta.

Furthermore, in those embodiments where biodegradable polymers are employed in Litner, the structure described bears no resemblance to the structure of Datta in which comprises an inner polymeric core and an outer polymeric layer each of which has a degradation rate different from the other.

Thus, one of ordinary skill in the art would neither have been motivated by nor found suggestion in the references to take even the *polymeric* materials (much less the metallic and ceramic materials) disclosed by Litner for eustachian tube stents and substitute them for the core material polymers of Datta, in a very different type of stent structure, absent the use of undue hindsight. *In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992), *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q. 1596, 1598-99 (Fed. Cir. 1988), *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

Nor has the examiner explained how there would have been any expectation of success for that substitution. *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (B.P.A.I. 1986). Also see MPEP 2143.02 and the cases cited therein. In this case there is *specific* reason to doubt success. Datta teaches strongly *away* from the use of metals in a lengthy discussion at col. 1, line 57, to col. 2,

line 18. See *In re Baird*, 16 F.3d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994). Also see the MPEP 2141.02 VI and the cases cited therein.

Reconsideration and withdrawal of the rejection over Datta in view of Litner are thus respectfully requested.

B. Rejection of Claims 1, 3, 6 and 9-21 under 35 U.S.C. 103(a) over Datta in view of Steinke et al US 6,623,521 (Steinke)

Claims 1, 3, 6 and 9-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Datta in view of Steinke. This rejection is respectfully traversed.

The differences between the present claims and Datta have been discussed above. The disclosure of Steinke does not provide the necessary elements to support a *prima facie* case of obviousness when taken together with Datta, anymore than does Litner.

As noted above, Datta teaches stents produced from biodegradable fibers that are readily passed from a body lumen after a predetermined period of time through normal flow of body fluids passing through the lumen, and in particular, stents for placement in the urethra. The fibers have an inner polymeric core and an outer polymeric layer each of which has a degradation rate different from the other. It is much preferred that the outer layer have a slower degradation rate than the inner or core layer. There is no disclosure that the outer layer "controls the rate at which the inner core material becomes flexible upon contact with bodily fluids," as required by the present claims. In other words a critical concept of applicant's claimed invention is not disclosed in Datta.

A further critical limitation of the present claims lacking in Datta is that the "inner core material is selected from a metallic material and a ceramic material." For that concept the examiner attempts to turn to Steinke, apparently relying on the listing of magnesium and calcium phosphate, among many other materials that are non-ceramic, non-metallic or biostable.

The concept of Steinke is a particular method of forming a stent from a plurality of flat sliding and locking elements. All of the claims and essentially the complete disclosure of Steinke are drawn to the mechanical aspects of that concept. Disadvantages of prior art devices relative to Steinke's design, including stents comprising fibers, can be found in the background. For example, with respect to "Wallstent" wire braid metallic stents, these were said to have the

disadvantage that metal prongs from the cutting process remained at the longitudinal ends of the wires. See, e.g., col. 1, lines 41-47.

Thus, even though biodegradable materials are employed in Steinke, two of which are either ceramic or metallic, the structure described bears no resemblance to the structure of Datta in which comprises fibers having an inner polymeric core and an outer polymeric layer, each of which has a degradation rate different from the other. With respect to the "two layers" referred to by the examiner, it is seen that "coatings" are disclosed in the paragraph at column 17, lines 31-37 of Steinke. There is no disclosure in Steinke, however, of an outer polymeric layer that has a biodegradation rate that is preferably slower than that of the underlying structure, nor does there appear to be a disclosure of an outer polymeric layer that is necessarily biodegradable at all. Furthermore, there is no indication that the coatings of Steinke will perform the function recited in the instant claims. Indeed, the outer coatings of Steinke are hydrogels, *Id.*, which would provide absolutely no control over the rate at which the inner core material becomes flexible upon contact with bodily fluids as claimed in claim 1. Coatings are disclosed to provide drug carriage, not to control the rate of increase in flexibility of the core material.

Moreover, where a biodegradable stent material is employed, drugs are preferably incorporated *into* the degradable matrix rather than in a coating on the matrix: See, e.g., col. 19, lines 3-6 (emphasis added): "Drugs and other bioactive compounds can be incorporated *into the degradable* matrices themselves *or coated on the non-degradable* stent materials, thereby providing sustained release of such compounds at the site of the stent." See also, col. 19, lines 49-57 (emphasis added): "The variety of compounds which may be used for coating metallic stents *or* for incorporating into degradable stent materials ... include antiplatelet agents..., antithrombin agents..., and antiproliferative agents...."

Thus, one of ordinary skill in the art would neither have been motivated by nor found suggestion in the references to take the biodegradable materials disclosed by Steinke and substitute them for the core material polymers of Datta, in a very different type of stent structure, absent the use of undue hindsight.

The Examiner urges that because Steinke discloses increasing the hardness of a material allows one to reduce the thickness of the same, it would have been obvious to replace the biodegradable inner core of Datta with a ceramic or metallic biodegradable material disclosed in

Steinke, in order to reduce the thickness of Datta's stent. However, as noted above, Datta teaches strongly *away* from the use of metals at col. 1, line 57, to col. 2, line 18. See, e.g., col. 1 line 65 to col. 2, line 2: "Also, since metals are typically much harder and stiffer than the surrounding tissues in a lumen, this may result in an anatomical or physiological mismatch, thereby damaging tissue or eliciting unwanted biologic responses."

Nor has the examiner explained how there would have been any expectation of success for that substitution. For example, there is no indication that the substitution proposed by the examiner will perform the functional requirements of the instant claims.

In view of the above, it is respectfully submitted that the combination posited by the examiner fails to support a *prima facie* case of obviousness. That is, there is no suggestion to combine the reference teachings absent the use of impermissible hindsight, there is a teaching away from the use of metals found in Datta, and there would have been no reasonable expectation of success. See the reported precedents cited in Section A.

Reconsideration and withdrawal of the rejection under 35 USC §103 over Datta in view of Steinke are thus respectfully requested.

C. **Rejection of Claims 1, 3, 6 and 9-21 under 35 U.S.C. 103(a) over Wang et al. WO98/56312 (Wang) in view of Steinke**

Claims 1, 3, 6 and 9-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Steinke. This rejection is respectfully traversed.

The issues here are essentially the same as to those described above in conjunction with Datta in view of Steinke, and the case law cited above is applicable here and incorporated by reference.

For example, like Datta, Wang describes stents having inner and outer biodegradable layers which exhibit different time periods of biodegradation. See Wang Abstract. There is no disclosure of a critical limitation of the present claims in which the outer layer controls the rate of increase of flexibility of the inner layer.

As with Datta above, the examiner recognizes that the claimed invention differs from Wang at least in that Wang does not disclose a biodegradable inner core material selected from a metallic material and a ceramic material. The examiner turns to Steinke to make up for this

deficiency, apparently relying on the listing of magnesium and calcium phosphate, among many other materials that are non-ceramic, non-metallic, or non-biodegradable.

As noted above, however, the concept of Steinke is a particular method of forming a stent from a plurality of flat sliding and locking elements. All of the claims and essentially the complete disclosure are drawn to the mechanical aspects of that concept. Disadvantages of prior art devices relative to Steinke's design, including various stent designs employed by Wang, can be found in the background of Steinke.

Moreover, unlike Wang, Steinke does not teach or suggest stents having inner and outer biodegradable layers which exhibit different time periods of biodegradation. As noted above, "coatings" are disclosed in the paragraph at column 17, lines 31-37 of Steinke, but there is no disclosure in Steinke of an outer polymeric layer that has a biodegradation rate that is different from that of an underlying biodegradable structure, or even of an outer polymeric layer that is necessarily biodegradable at all. Further, where a biodegradable stent material is employed, drugs are preferably incorporated *into* the degradable matrices rather than on a coating.

Thus, one of ordinary skill in the art would neither have been motivated by nor found suggestion in the references to take the biodegradable materials disclosed by Steinke and substitute them for the core material polymers of Wang, in a very different type of stent structure, absent the use of undue hindsight.

As above, the examiner argues that because Steinke discloses increasing the hardness of a material allows one to reduce the thickness of the same, it would be obvious to replace the biodegradable inner core of Wang with a ceramic or metallic biodegradable material disclosed in Steinke, in order to reduce the thickness of Wang's stent. However, as noted above, the prior art (Datta) teaches strongly *away* from the use of metals, which may, for example, result in an anatomical or physiological mismatch, thereby damaging tissue or eliciting unwanted biologic responses. Relatedly, Wang's stated goal is to exhibit sufficient hoop strength to support the passage wall in which the stent is implanted and yet be flexible and compliant. See page 1, lines 23-24. The substitution of a hard material as urged by the examiner, however, is antithetical to achieving such flexibility and compliancy.

Finally, the examiner has not explained how there would have been any expectation of success for the proposed substitution. For example, there is no indication that the substitution proposed by the examiner will perform the functional requirements of the instant claims.

Reconsideration and withdrawal of the rejection over Wang in view of Steinke are thus respectfully requested.

D. Rejection of Claims 5 and 7 under 35 U.S.C. 103(a) over Wang in view of Steinke further in view of Langer et al. US 6,160,084 (Langer)

Claims 5 and 7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wang in view of Steinke and Langer. This rejection is respectfully traversed.

Wang and Steinke have been discussed in Section C. Claim 5 requires that the covering material be a "hydrophobic surface erodable polymer." Claim 7 requires that the covering material be "a shape memory biodegradable polymer."

The examiner refers to column 12, lines 59-67 of Langer, for a teaching of hydrophobic shape memory polymers. Although that disclosure includes using such a hydrophobic polymer to temporarily protect an underlying hydrolytically cleavable polymer, it relates to a "bulk" polymer and is in no way related to the stents of the other references. Thus this reference fails to provide a teaching of the here relevant concept. Its inclusion in the combination of references relied on merely emphasizes the application of undue hindsight discussed above, with citation of *Akzo* and *Loctite* as authority.

Reconsideration and withdrawal of the rejection over Wang in view of Steinke and Langer are thus respectfully requested.

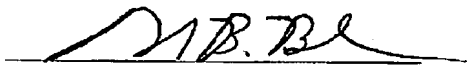
CONCLUSION

Applicant submits all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

FEES

If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

Respectfully submitted,



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